REMARKS

Claim amendments

Claims 24-31 and 33 are canceled.

Claim 32 has been amended to recite a method for selecting one or more vaccine compositions from among a group consisting of two or more distinct vaccine compositions for assessment in a human, said vaccine compositions each comprising one or more nucleic acid molecules encoding one or more antigens which comprise the same $CD8^+$ T cell epitope, using monoclonal human $CD8^+$ T cells. Support for the amendment can be found, for example, on page 10, lines 17-24 of the specification.

New Claims 44-47 depend from Claim 32. Support for Claim 44 can be found, for example, on page 10, lines 25-30; support for Claim 45 can be found, for example, on page 10, lines 17-24; support for Claim 46 can be found, for example, on page 9, line 29; and support for Claim 47 can be found, for example, on page 5, line 20 of the specification.

Claim 35 has been amended to recite a method for optimizing the T cell response against a T cell epitope comprising the steps of separately contacting human antigen presenting cells in culture with each of two or more distinct vaccine compositions, wherein each of the distinct vaccine compositions comprises one or more nucleic acid molecules encoding one or more antigens which comprise the same specific T cell epitope, under conditions suitable for said human antigen presenting cells to take up nucleic acid molecules and permit the human antigen presenting cells to produce one or more processed antigens. Support for the amendment can be found, for example, on page 8, lines 13-23; page 15, lines 23-31; and Examples 1-3 of the specification.

New Claims 36-43 depend from Claim 35. Support for Claims 36-40 can be found, for example, on page 10, lines 8-30; support for Claim 41 can be found, for example, on page 9, line 29; support for Claim 42 can be found, for example, on page 5, line 20; and support for Claim 43 can be found, for example, on page 11, line 6 of the specification.

New Claim 48 has been added and is directed to a method for selecting one or more vaccine compositions from among a group consisting of two or more distinct vaccine compositions for assessment in a human, said vaccine compositions each comprising one or more nucleic acid molecules encoding one or more antigens which comprise the same $CD4^+$ T cell

epitope, using monoclonal human $CD4^+$ T cells. Support for the amendment can be found, for example, on page 10, lines 8-16 of the specification.

New Claims 49-53 depend from Claim 44. Support for Claim 49 can be found, for example, on page 11, line 6; support for Claim 50 can be found, for example, on page 10, lines 25-30; support for Claim 51 can be found, for example, on page 10, lines 8-16; support for Claim 52 can be found, for example, on page 9, line 29; and support for Claim 53 can be found, for example, on page 5, line 20 of the specification.

No new matter has been added.

Rejection of Claim 35 under 35 U.S.C. §112, first paragraph

Claim 35 is rejected under 35 U.S.C. §112, first paragraph "as failing to comply with the written description requirement" (Office Action, page 2). The Examiner interprets Claim 35 "as literally reading, in step (a), that one contacts APCs within a single culture with two or more distinct vaccine compositions", however, the disclosure recites 'the vaccine composition' in the singular, rather than 'two or more'" (Office Action, pages 2-3).

Applicants respectfully disagree. To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention (*Vas-Cath, Inc. v. Mahurkar*, 19 U.S.P.Q.2d 1111,1116 (Fed. Cir. 1991)).

In the specification as filed, Applicants clearly teach that "the invention provides a method for selecting one or more vaccine compositions from among a group of vaccine compositions for *in vivo* assessment" (specification, page 2, lines 14-16). In addition, Applicants teach that:

> the present invention enables the rapid assessment and comparison of a large number of potential vaccine compositions. For any given disease or pathogen, for example, a variety of antigens can be assessed. For example, a set of vaccine compositions which each include different antigens or portions of antigens from a particular pathogen can be compared. Further, for a given antigen, set of antigens, or nucleic acid molecule encoding such antigen(s), a variety of formulations can be assessed. For example, a set of vaccine compositions including the same antigen or antigens, but different vectors, adjuvants, concentrations, vehicles or excipients can be compared to determine the conditions necessary for optimal efficacy (specification, page 15, lines 23-31).

Based on Applicants teaching in the specification, one of skill in the art would reasonably conclude that one could assess a very large number of potential vaccine composition by contacting antigen presenting cells (APCs) within a single culture with two or more distinct vaccine compositions. For example, based on Applicants' disclosure, one of skill in the art would reasonably conclude that one could assess a very large number of potential vaccine compositions in a variety of formulations by contacting antigen presenting cells (APCs) within a single culture with two or more distinct vaccine compositions in the same or a similar formulation. That is, APCs within a single culture that have been contacted with two or more nucleic acid molecules that encode a particular antigen that are formulated in a ***variety of viral vectors*** can be assessed, and compared to APCs within a single culture that have been contacted with two or more naked DNAs encoding the same antigen that are formulated in a ***variety of liposomes*** to determine whether the vaccine is optimized in a viral vector formulation or in a liposome formulation. Once this is determined, then the optimized formulation (*e.g.*, either the viral vector formulations or the liposome formulations) can be further assessed to determine which particular formulation is optimal. For example, if it is found that the viral vector formulations are optimal, then APCs within a single culture can be separately contacted with each viral vector formulation to determine the optimal viral vector formulation for the particular nucleic acid molecule encoding the particular antigen which would be suitable for *in vivo* assessment.

Clearly, Applicant describes the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.

However, as the Examiner has pointed out, "claim 35 corresponds to issued claim 2" in U.S. Patent No. 6,627,407 (Office Action, page 4). Therefore, Claim 35 has been amended to recite a method for optimizing the T cell response against a T cell epitope comprising the steps of separately contacting human antigen presenting cells in culture with each of two or more distinct vaccine compositions, wherein each of the distinct vaccine compositions comprises one or more nucleic acid molecules encoding one or more antigens which comprise the same specific T cell epitope, under conditions suitable for said human antigen presenting cells to take up nucleic acid molecules and permit the human antigen presenting cells to produce one or more processed antigens.

Rejection of Claim 35 under 35 U.S.C. §112, first paragraph

Claim 35 is rejected under 35 U.S.C. §112, first paragraph "as containing subject matter, which was not described in the specification in such a way as to enable one skilled in the relevant art to make and/or use the invention" (Office Action, page 3). The Examiner states that "Claim 35 fails to enable the selecting of 'the vaccine composition is possessing an optimal response' as required in step (c)" (Office Action, page 3).

Applicants respectfully disagree. "The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation" (*United States v. Teletronics, Inc.* 8 U.S.P.Q.2d, 1217, 1223 (Fed. Cir. 1988).

Applicant refers the Examiner to the example above used to illustrate how at the time of the invention, Applicant was in possession of the claimed method. Applicants have also enabled the claimed method for use in assessing a very large number of potential vaccine compositions in a variety of formulations by contacting antigen presenting cells (APCs) within a single culture with two or more distinct vaccine compositions in the same or a similar formulation. That is, APCs within a single culture that have been contacted with two or more nucleic acid molecules that encode a particular antigen that are formulated in a ***variety of viral vectors*** can be assessed, and compared to APCs within a single culture that have been contacted with two or more naked DNAs encoding the same antigen that are formulated in a ***variety of liposomes,*** to determine whether the vaccine is optimized in a viral vector formulation or in a liposome formulation without undue experimentation. Clearly, one reasonably skilled in the art could determine the T cell response to the processed antigen, and select the vaccine composition possessing an optimal response as stated in step (c) of Claim 35 without undue experimentation.

Applicant has provided an enabling disclosure for the full scope of the claimed invention.

However, as the Examiner has pointed out, "claim 35 corresponds to issued claim 2" in U.S. Patent No. 6,627,407 (Office Action, page 4). Therefore, Claim 35 has been amended to recite a method for optimizing the T cell response against a T cell epitope comprising the steps of separately contacting human antigen presenting cells in culture with each of two or more distinct vaccine compositions, wherein each of the distinct vaccine compositions comprises one or more

nucleic acid molecules encoding one or more antigens which comprise the same specific T cell epitope, under conditions suitable for said human antigen presenting cells to take up nucleic acid molecules and permit the human antigen presenting cells to produce one or more processed antigens

Rejection of Claim 24-32 and 35 under 35 U.S.C. §101

Claims 24-32 and 35 are rejected under 35 U.S.C. §101 "as claiming the same invention as that of claims 1-9 and 12 of prior U.S. Patent No. 6,627,407" (Office Action, page 4).

Claims 24-31 have been canceled. Claim 32 has been amended to recite a method for selecting one or more vaccine compositions from among a group consisting of two or more distinct vaccine compositions for assessment in a human, said vaccine compositions each comprising one or more nucleic acid molecules encoding one or more antigens which comprise the same $CD8^+$ T cell epitope, using monoclonal human $CD8^+$ T cells. Claim 35 has been amended to recite a method for optimizing the T cell response against a T cell epitope comprising the steps of separately contacting human antigen presenting cells in culture with each of two or more distinct vaccine compositions, wherein each of the distinct vaccine compositions comprises one or more nucleic acid molecules encoding one or more antigens which comprise the same specific T cell epitope, under conditions suitable for said human antigen presenting cells to take up nucleic acid molecules and permit the human antigen presenting cells to produce one or more processed antigens. U.S. Patent No. 6,627,407 does not include the same invention of Claims 32 and 35, particularly as amended.

The amendments obviate the rejection under 35 U.S.C. §101.

Rejection of Claims 33 and 34 under the judicially created doctrine of obviousness-type double patenting

Claims 33 and 34 are rejected under the judicially created doctrine of obviousness-type double patenting "as being unpatentable over claims 1, 7 and 9-11 of U.S. Patent No. 6,627,407" (Office Action, pages 4-5).

Claim 33 has been canceled. Claim 34 depends from Claim 32, which has been amended to recite a method for selecting one or more vaccine compositions from among a group

consisting of two or more distinct vaccine compositions for assessment in a human, said vaccine compositions each comprising one or more nucleic acid molecules encoding one or more antigens which comprise the same $CD8^+$ T cell epitope, using monoclonal human $CD8^+$ T cells.

A terminal disclaimer in compliance with 37 C.F.R. §1.321(c), together with the requisite Statement under 37 C.F.R. §3.73(b), are being filed concurrently, thereby obviating the rejection. The statutory fee in the amount of $110.00 for filing the disclaimer is also enclosed.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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Dated: November 3, 2004